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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/930,871	08/15/2001	C. Alexander Turner JR.	LEX-0216-USA	1901

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LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER

TURNER, SHARON L

ART UNIT PAPER NUMBER

1647

DATE MAILED: 02/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/930,871

Applicant(s)

TURNER ET AL.

Examiner

Sharon L. Turner

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 85-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 85-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Response to Amendment

1. The amendment filed 11-17-03 has been entered into the record and has been fully considered.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.
3. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.
4. Claims 1, 3-4, and 6-8 are pending.

Election/Restriction

5. Applicant's election without traverse of Group VI, nucleic acids encoding SEQ ID NO:12 is noted. All pending claims are drawn to the elected invention.

Claim Rejections - 35 USC § 101

6. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

7. Claims 1, 3-4 and 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification discloses isolated novel human proteins (NHPs) that share structural similarity with mammalian ion channel proteins, in particular sodium ion channel proteins and voltage-gated sodium ion channel proteins, see in particular specification pp. 1-2, paragraph spanning. Also disclosed are the related reagents and

methods of use including to nucleic acids, peptides antibodies, vectors, host cells and methods of producing the recombinant peptide. While the specification generically discusses these types of peptides, the specification fails to note any particular data specific to SEQ ID NO:12 other than the particular SEQ ID NO and fails to establish the peptides use in any particular method of use, treatment, diagnostic or prognostic related to any specific function or disorder. While the artisan recognizes multiple types of sodium ion channels with divergent structure and function, the artisan fails to recognize a specific and substantial use of SEQ ID NO:12. Further, the specification fails to teach the particular function and/or significance of the SEQ ID NO:12 molecule. The molecule is not noted to be any particular type of sodium channel, i.e., voltage gated, sodium/potassium ion pump or otherwise, and the specification fails to teach how the purported sodium ion channel may be used or manipulated so as to provide for any particular use, function or effect in any particular tissue, disorder, prognostic, diagnostic, treatment or disease. Thus, the disclosed nucleic acids merely constitute research reagents for further experimentation to discover a "real-world" use for the nucleic acids. The recited uses also do not constitute a well-established utility because the structure and function of the molecule is not established in the prior art. As recognized by Skolnick et al., Trends in Biotech., 18(1):34-39, 2000, the skilled artisan is well aware that there is an unpredictable nature in the ability of encoding nucleic acids to predict structural and functional activities for any particular protein or protein family, and particularly in ion function. Even when highly homologous and conserved residues are known only experimental research can confirm the artisan's best guess, see in

particular Skolnick, abstract and Box 2. Thus, the assignment of instant SEQ ID NO:12 as a purported sodium ion channel based upon homology is not sufficient based on the knowledge of the skilled artisan and the data presented in instant specification to provide either specific or substantial utility to the claimed sequences. The artisan would not know how to use the molecules to provide for significant or substantial benefit. The function and significance of the nucleic acids encoding the peptide, remain to be established. Thus, for these reasons there does not appear to be either a specific and substantial asserted utility or well-established utility for the claimed nucleic acid sequences.

Applicants argue in the response of 11-17-03 that the invention provides a number of utilities that meet the requirements such as forensic analysis, as supported at pp. 8, lines 2-7, p. 13, lines 9-20 and in the sequence listing. Applicants argue that the utility is to identify individual members based simply on the presence or absence of one or more of the unique polymorphisms and that at worst case the marker would be useful to distinguish 50% of the population. Applicants additionally argue that the noted sequence shares identity and high homology with other prior art sequences noted in GenBank databases as corresponding to human voltage gated sodium channel subunits. Accordingly applicants perceive that no question can arise as to the utility of the peptide. Applicants further argue utility of the invention with respect to DNA chips, tracking expression including as noted on chromosome 2 and in screening methods for targets of drug discovery.

Applicants arguments filed 11-17-03 have been fully considered but are not

persuasive. The specification at p. 8, lines 2-7, p. 13, lines 9-20 and in the sequence listing merely describe methods for identifying polymorphisms and the particular polymorphisms as noted at p. 13 and in the sequence listing. The specification does not actively support the use of the identified polymorphism as useful in forensic analysis and the Examiner finds no direct support for such use in the specification as filed. Further, the Examiner fails to acknowledge that such forensic analysis is a well established utility within the art and no evidence to support such has been filed. Moreover, the utility of forensic analysis is not deemed to be either specific or substantial in that the utility merely relies on the classification of the compounds amongst others of it's broad class, namely polynucleotides. While applicants argue that the marker would be useful to distinguish 50% of the population, the Examiner notes that no such evidence is of record regarding the penetrance or proportion of individuals in the general population that possess one of the polymorphisms or the other. No data thus supports the conclusion that the marker is useful to test either positively or negatively amongst individuals.

Moreover, mere placement amongst members of voltage-gated sodium channel members fails to provide specific and substantial utility to the unique sequence. For example, the placement in this broad class lends nothing to the specific function or the significance to the channel subunit to sodium channel function, see in particular Stein, Channels, carriers and Pumps, Academic Press, 1990, pp:221-269 and Lehmann-Horn, Phys. Reviews, 79(4):1317-1372, 1999 which evidence as previously set forth, sodium ion channel subunits differ substantially in function and associated utility. It is

undisclosed and undiscovered if the subunit increases or decreases ion transport and further the function of ion transport alone fails to disclose how the channel subunit can be used to mediate any particular biological process, diagnostic, prognostic, forensic analysis, drug testing, etc.

The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-tumor activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are “useful” to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of “useful” as it appears in 35 U.S.C. '101, which requires that an invention must have either an immediately apparent or fully disclosed “real world” utility. The court held that:

The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. . . . [u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field. . . . a patent is not a hunting license. . . . [i]t is not a reward for the search, but compensation for its successful conclusion.

The instant claims are drawn to a nucleic acid sequence identified as encoding a voltage-gated sodium ion channel subunit. However, the specific function of the subunit within the broad class is yet to be determined. Accordingly, the function or biological significance of the molecule remains to be discovered. There is no evidence of record

or any line of reasoning that would support a conclusion that the sequences were, as of the filing date, useful for diagnosis, prevention and/or treatment or that the polymorphism was specifically useful amongst any other polymorphic sequence for forensic analysis, DNA testing and methods of screening for drugs. Until some actual and specific significance can be attributed to the protein, or the gene encoding it, one of ordinary skill in the art would be required to perform additional experimentation in order to determine how to use the claimed invention. It is noted that sodium channel subunits as a broad class of proteins are not recognized as sharing any specific, substantial or well established utility. Thus, there is no specific and substantial asserted utility or well established utility for the claimed invention.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1, 3-4 and 6-8 are also rejected under 35 U.S.C. 112, first paragraph.

Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants argue in the response of 11-17-03 as noted above with respect to utility.

Applicants arguments filed 11-17-03 have been fully considered but are not persuasive for the same reasons as noted above.

Status of Claims

10. No claims are allowed.
11. The claimed invention is free of the prior art. WO0138564 of record as reference CH is the closest prior art of record.

Conclusion

12. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

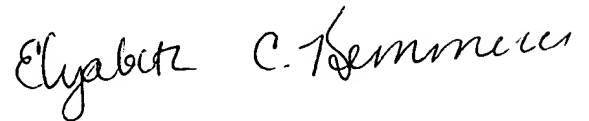
13. Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1647

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (571) 272-0894. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (571) 272-0887.

Sharon L. Turner, Ph.D.
February 24, 2004

A handwritten signature in cursive script that reads "Elizabeth C. Kemmerer".

ELIZABETH KEMMERER
PRIMARY EXAMINER